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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,474	08/04/2006	Katsuo Sueishi	50026/055001	2218

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EXAMINER	
HAMA, JOANNE	
ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
03/20/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/549,474	SUEISHI ET AL.	
	Examiner	Art Unit	
	JOANNE HAMA	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/4/05;8/22/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant filed a response to the Restriction Requirement of October 10, 2007 on January 11, 2008. Applicant elected Group 1 with traverse and the species "soluble FGF receptor". Applicant indicates that in an interview with the Examiner on December 20, 2007 that claims 2, 3, 7, 8 of Group 2 should be included in the examination as the method involves "the step of administering a vector encoding a protein or a nucleic acid which inhibits a signal transduction that is mediated by fibroblast growth factor-2 (FGF2)-FGF receptor 1-Ras-Raf-MAP kinase." As such, claim 1 involves administering a vector and this vector encodes either a protein or a nucleic acid and claims 2, 3, 7, 8 of Group 2 should be included as these claims read on methods of administering a vector encoding a nucleic acid (Applicant's response, page 2). In response, from what the Examiner understood in the interview, Dr. Tittel had indicated that what was meant by the claims was that mRNA is the nucleic acid produced by the vector and not antisense or siRNA (see restriction, page 3, which indicates that the nucleic acid being expressed was interpreted as being antisense or siRNA). In this respect, since protein expression of the claims depends on mRNA expression, the Groups will be rejoined and be readable on mRNA as the nucleic acid.

Claims 1-10, drawn to a method of treating an inflammatory disease comprising administering a vector encoding a protein or mRNA which inhibits the FGF2-FGFR1-Ras-Raf-MAP kinase pathway and to a composition comprising a vector encoding a

protein or mRNA which inhibits the FGF2-FGFR1-Ras-Raf-MAP kinase pathway, are under consideration. Per species election, the protein/mRNA is "soluble FGF receptor."

Information Disclosure Statement

Applicant filed Information Disclosure Statements on November 4, 2005 and August 22, 2007. The IDSes have been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 9, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Seddon et al., US Patent 5,491,220, patented February 13, 1996.

Seddon et al. teach that soluble FGF receptor proteins are constructed by cloning of the extracellular region of murine FGF receptor 1 (FGFR-1; flg) into an alkaline phosphatase-tag expression vector (Seddon et al., 3rd parag. under Example 6).

It is noted that while claims 6 and 10 indicate an intended use of the soluble FGF receptor to treat osteoarthritis, the intended use does not provide any structural limitations of the soluble FGFR that distinguish the art from the claimed invention. As such, Seddon et al. anticipate claims 6, 9, 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seddon et al., US Patent 5,491,220, patented February 13, 1996, in view of Yu et al., 1997, Genes to Cells, 2: 457-466.

As discussed above, Seddon et al. teach that cloning the extracellular region of murine FGF receptor yields a soluble FGFR-1. While Seddon et al. provide this teaching, they do not teach the use of a Sendai viral vector.

Yu et al. teach a system for expressing recombinant HIV-1 gp120 protein via a Sendai viral vector. The open reading frame (ORF) of gp120 was inserted in the N gene of pSEV18+b. gp120 gene expression was initiated by the S signal which was originally used for N gene expression in the wild-type SeV (Yu et al., page 458, under "Insertion of an HIV-1 gp120 coding sequence into the pSEV18+ plasmid and virus recovery", see also Figure 1). mRNA and protein of gp120 expressed from the recombinant Sendai virus was detected (Yu et al., Figure 2).

All the component parts are known in Seddon et al. and Yu et al. The only difference is the combination of the “old elements” into a single composition of a Sendai viral vector comprising a nucleic acid sequence encoding soluble kinase-deficient FGF

receptor. Thus, it would have been obvious to one or ordinary skill to use the Sendai viral vector to express recombinant soluble FGF receptor as Yu et al. teach that Sendai viral vector can be used to express recombinant mRNA and protein and Seddon et al. teach a that nucleic acid sequence encoding soluble kinase-deficient FGF receptor can be expressed.

Claims 1, 4, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al., 1998, Cancer Research 58: 3362-3369, in view of Yu, US Patent 6,811,788 B2, patented November 2, 2004, Walsh, 1999, Rheumatology, 38: 103-112, Seddon et al., US Patent 5,491,220, patented February 13, 1996.

Tanaka et al. teach that viral vectors (retroviral and adenoviral) that transduce the angiostatin cDNA can be used to inhibit angiogenesis in vivo (Tanaka et al., abstract). While Tanaka et al. teach treatment of angiogenesis using angiostatin, they do not teach using soluble FGFR-1.

Yu teaches that basic FGF-soluble receptor (also known as soluble FGFR-1) can be used in anti-angiogenic applications (Yu, col. 4, line 62).

Because both Tanaka et al. and Yu teach methods of treating angiogenesis, it would have been obvious to one skilled in the art to substitute angiostatin cDNA with that of basic FGF-soluble receptor to achieve the result of treating angiogenesis.

It is noted that angiogenesis is part of the pathology of osteoarthritis. Walsh teaches that during osteoarthritis, new vessels invade the cartilage from the underlying bone (Walsh, page 105, 2nd parag. under "Sites of angiogenesis in arthritis").

Angiogenesis in arthritis exacerbate inflammation, synovial proliferation and invasion, and osteophyte formation (Walsh, page 105, parag. under “Roles of angiogenesis during synovitis”). It is also noted that a nucleic acid construct comprising soluble FGFR-1 was known at the time of filing, e.g. Seddon et al., 3rd parag. under Example 6.

Thus, the claims are obvious.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al., 1998, Cancer Research 58: 3362-3369, in view of Yu, US Patent 6,811,788 B2, patented November 2, 2004, Yu et al., 1997, Genes to Cells, 2: 457-466.

As discussed above, given the combined teachings of Tanaka et al. and Yu, and artisan would have arrived at a method of treating an inflammatory disease comprising administering a nucleic acid construct comprising administering a nucleic acid sequence encoding soluble FGFR-1. While the combined teachings provide this guidance, the combined teachings do not teach a Sendai virus vector.

Yu et al. teach a system for expressing recombinant HIV-1 gp120 protein via a Sendai viral vector. The open reading frame (ORF) of gp120 was inserted in the N gene of pSEV18+b. gp120 gene expression was initiated by the S signal which was originally used for N gene expression in the wild-type SeV (Yu et al., page 458, under "Insertion of an HIV-1 gp120 coding sequence into the pSEV18+ plasmid and virus recovery", see also Figure 1). mRNA and protein of gp120 expressed from the recombinant Sendai virus was detected (Yu et al., Figure 2).

Because the combined teachings of Tanaka et al. and Yu lead to retroviral and adenoviral vectors comprising a nucleic acid sequence encoding soluble FGFR-1 and because Yu et al. teach that Sendai virus can be used to deliver a transgene of interest, it would have been obvious to one skilled in the art to substitute the viral vectors to achieve the predictable result of expressing soluble FGFR-1 with a Sendai viral vector.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Joanne Hama, Ph.D./
Examiner, Art Unit 1632